

Message Text

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ACTION HEW-06

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TO SECSTATE WASHDC 6497

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E.O. 11652: N/A

TAGS: TBIO, PL

SUBJECT: DHEW: REQUEST FOR INFORMATION ON COMPENSATION TO
SUBJECTS INJURED THROUGH BIO-MEDICAL RESEARCH
EXPERIMENTATION

REF STATE 170457

1. COPIES OF PERTINENT POLISH LEGISLATION AND OTHER MATERIALS
RE DHEW REQUEST BEING POUCHED TO DR. QUINN, FOGARTY
INTERNATIONAL CENTER.

2. IN VIEW OF SHORT DEADLINE, THE FOLLOWING IS A RESUME OF
COMPENSATION PROCEDURES FOR INDIVIDUALS INJURED IN BIOMEDICAL
EXPERIMENTATION:

A. ALL EXPERIMENTAL SUBJECTS MUST SIGN STATEMENT INDICATING
THEY ARE AWARE THAT THE THERAPY THEY WILL UNDERGO IS
EXPERIMENTAL;

B. POLISH LAW MAKES NO DISTINCTION BETWEEN PHYSICIAN AND
RESEARCH INSITUTE LIABILITY FOR INJURY INCURRED IN EXPERI-
MENTATION OR THROUGH NORMAL THERAPY;

C. SUBJECTS CLAIMING INJURY CAN SUE THE PHYSICIAN/INSTITUTE
UNDER PROVISIONS IN POLISH CIVIAL AND PENAL LAW. LAW PRO-
VIDES FOR INDEMNIFICATION OF INJURED SUBJECTS (COST OF
MEDICINE, TREATMENT, LOSS OF EARNINGS, BURIAL) BY GUILTY
PARTY, WHO MAY ALSO BE SUBJECT TO FINE AND IMPRISONMENT. IN
THE CASE OF A GOVERNMENT BIO-MEDICAL RESEARCH INSTITUTION
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(IN POLAND PRACTICALLY ALL BIO-MEDICAL RESEARCH IS PERFORMED

BY THE GOVERNMENT), THE INJURED SUBJECT IS INDEMNIFIED BY THE POLISH GOVERNMENT;

D. A TEAM OF SPECIALISTS FROM A FORENSIC MEDICAL FACULTY FROM ONE OF THE POLISH MEDICAL UNIVERSITIES IS AVAILABLE TO THE COURT IN MAKING ITS DECISIONS.

3. PROTECTION OF HUMAN SUBJECTS IN BIO-MEDICAL RESEARCH IS A RESPONSIBILITY OF THE SCIENTIFIC COUNCIL OF THE MINISTRY OF HEALTH. FOR FOLLOW UP, HEW SHOULD CONTACT DR. EDWARD RUZYLO, CHAIRMAN, SCIENTIFIC COUNCIL, MINISTRY OF HEALTH AND SOCIAL WELFARE, MIODOWA STREET 15, WARSAW.

4. IN DR. RUZYLOO'S ABSENCE FROM WARSAW, SCIATT DISCUSSED MATTER WITH DR. WLODZIMIERZ KURYLOWICZ, DIRECTOR OF THE STATE INSTITUTE OF HYGIENE, AND FORMER CHAIRMAN OF THE SCIENTIFIC COUNCIL. DR. KURYLOWICZ STATED CASES OF HUMAN SUBJECTS INJURED IN BIO-MEDICAL EXPERIMENTATION ARE VERY RARE IN POLAND, AND THE STATE INSTITUTE OF HYGIENE HAS ONLY HAD ONE SUCH CLAIM IN ITS HISTORY. AS A MATTER OF INTEREST TO HEW, THE CASE INVOLVED A HEW-SUPPORTED RESEARCH PROJECT ON ISONIAZID PROPHYLAXIS (PROJECT 05-333-2) IN WHICH A SUBJECT CLAIMED LIVER DAMAGE DUE TO TREATMENT. THE CASE WAS THROWN OUT OF COURT WHEN IT WAS DETERMINED THAT THE INDIVIDUAL RECEIVED ONLY PLACEBOS IN THIS DOUBLE-BLIND EXPERIMENT. DAVIES

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